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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,749	03/03/2006	Lukas C. Amler	D0304 NP	9819

23914   7590   01/08/2008
LOUIS J. WILLE
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
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EXAMINER
GUSSOW, ANNE

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
01/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@BMS.COM
patents@bms.com
eileen.immordino@bms.com

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-4* is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claim(s) *1-4* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a) ☐ All   b) ☐ Some * c) ☐ None of:

        1. ☐ Certified copies of the priority documents have been received.

        2. ☐ Certified copies of the priority documents have been received in Application No. _____.

        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
     Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
     Paper No(s)/Mail Date _____.

5) ☐ Notice of Informal Patent Application

6) ☒ Other: *Sequence alignment*.

DETAILED ACTION

Election/Restrictions

1.   Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which

are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to

be linked by a special technical feature. The special technical feature recited in claim 1

is a biomarker selected from the biomarkers in Table 4. In view of this Augustus (US

PG PUB 2002/0102532, filed October 3, 2001) reads on the claim. Augustus teaches a

method of treating cancer with agents targeting gene expression products. Augustus

teaches one of these agents (SEQ ID No. 417) that is identical to 3-hydroxy-3-

methylglutaryl-Coenzyme A synthase 2 (SEQ ID No. 1 in table 4) of the instant

invention. Therefore the technical feature recited in claim 1 is not special. Accordingly

the groups are not so linked at to form a single general concept under rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to

elect a single invention to which the claims must be restricted.

Groups 1-139, claim(s) 1-4, drawn to a method for identifying a mammal that will
respond therapeutically to a method of treating cancer by measuring the level of a
biomarker selected from the listing in Tables 4 and 5. Each biomarker is a separate
group.

2.   The inventions listed as Groups 1-139 do not relate to a single general inventive

concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: As set forth above, in view of the teachings of Augustus, the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

3.   Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4.   Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by

a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-

6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

Anne M. Gussow
January 2, 2008

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<!--StartFragment-->RESULT 1
US-09-969-708-417
; Sequence 417, Application US/09969708
; Patent No. US20020102532A1
; GENERAL INFORMATION:
;  APPLICANT: Augustus, Meena
;  TITLE OF INVENTION: Cancer Gene Determination and Therapeutic Screening Using Signa
;  TITLE OF INVENTION:  Sets
;  FILE REFERENCE: 689290-70
;  CURRENT APPLICATION NUMBER: US/09/969,708
;  CURRENT FILING DATE:  2001-10-03
;  PRIOR APPLICATION NUMBER: US/60/237,606
;  PRIOR FILING DATE: 2000-10-03
;  PRIOR APPLICATION NUMBER: US/60/237,608
;  PRIOR FILING DATE: 2000-10-03
;  PRIOR APPLICATION NUMBER: US/60/237,425
;  PRIOR FILING DATE: 2000-10-03
;  NUMBER OF SEQ ID NOS: 658
;  SOFTWARE: PatentIn version 3.0
; SEQ ID NO 417
;   LENGTH: 2058
;   TYPE: DNA
;   ORGANISM: Homosapiens
US-09-969-708-417

  Query Match              100.0%;  Score 2058;  DB 3;  Length 2058;
  Best Local Similarity    100.0%;  Pred. No. 0;
  Matches 2058; Conservative   0;  Mismatches   0;  Indels   0;  Gaps   0;

Qy        1 CGGTTTCTGCTGGGTTTCTGAACTGCTGGGTTTCTGCTTGCTCCTCTGGAGATGCAGCGT 60
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Qy       61 CTGTTGACTCCAGTGAAGCGCATTCTGCAACTGACAAGAGCGGTGCAGGAAACCTCCCTC 120
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Qy    601  TCCTGGGATGGTCGTTATGCCATGGTGGTCTGTGGAGACATTGCCGTCTATCCCAGTGGT  660
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Qy    661  AATGCTCGTCCCACAGGTGGGGCCGGAGCTGTGGCTATGCTGATTGGCCCAAAGGCCCCT  720
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Qy    841  CGGGCCTTGGATCGATGTTACACATCATACCGTAAAAAAATCCAGAATCAGTGGAAGCAA  900
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Qy    901  GCTGGCAGCGATCGACCCTTCACCCTTGACGATTTACAGTATATGATCTTTCATACACCC  960
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Qy   1021  AGCAGTGACACACAAACCAGCTTATATAAGGGGCTGGAGGCTTTCGGGGGGCTAAAGCTG  1080
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Qy   1081  GAAGACACCTACACCAACAAGGACCTGGATAAAGCACTTCTAAAGGCCTCTCAGGACATG  1140
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Qy   1141  TTCGACAAGAAAACCAAGGCTTCCCTTTACCTCTCCACTCACAATGGGAACATGTACACC  1200
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Qy   1201  TCATCCCTGTACGGGTGCCTGGCCTCGCTTCTGTCCCACCACTCTGCCCAAGAACTGGCT  1260
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Qy   1261  GGCTCCAGGATTGGTGCCTTCTCTTATGGCTCTGGTTTAGCAGCAAGTTTCTTTTCATTT  1320
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Qy   1321  CGAGTATCCCAGGATGCTGCTCCAGGCTCTCCCCTGGACAAGTTGGTGTCCAGCACATCA  1380
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Qy   1381  GACCTGCCAAAACGCCTAGCCTCCCGAAAGTGTGTGTCTCCTGAGGAGTTCACAGAAATA  1440
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Qy     1441  ATGAACCAAAGAGAGCAATTCTACCATAAGGTGAATTTCTCCCCACCTGGTGACACAAAC 1500
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Qy     1981  TGAATCTCCAAATTTTGTACCTTGTTCTAAGCTAATATATAGCAATTAAAAAGAGAGAAA 2040
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Db     1981  TGAATCTCCAAATTTTGTACCTTGTTCTAAGCTAATATATAGCAATTAAAAAGAGAGAAA 2040

Qy     2041  GAGAAAAAAAAAAAAAAA 2058
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Db     2041  GAGAAAAAAAAAAAAAAA 2058
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